

April 13, 2002

TO: Jim Wilson
FROM: Don Barnes
SUBJECT: EPA's Science Advisory Board and peer review

Thanks for the opportunity to comment on SAB *vis a vis* the upcoming SRA conference on Peer Review. There is nomenclature confusion within the Agency, so it is not surprising that there is confusion outside the Agency, as well.

Peer Review and Peer Involvement

As described in the Agency's *Peer Review Handbook*, the Agency makes a distinction between Peer Review and Peer Involvement.

Peer Review is the outside, independent, critical review with which we are all familiar. It usually occurs at the end of the process; i.e., after the Agency has examined a scientific issue and has developed a position upon which it will construct its policy position. For example, for the NAAQS, the Agency generates a massive Criteria Document and brings it to the SAB (CASAC, specifically) for critical peer review; i.e., "Did we find all of the science and have we assessed it appropriately?"

Once the SAB feels that the Criteria Document is in good shape, the Agency goes off and develops a Staff Paper that describes how the Agency will take the science in the Document and use it to develop a policy position; i.e., "And the permitted level of ozone will be...." The Staff Paper is brought to the SAB who are asked "Is the Agency's position (which is constructed on the scientific foundation that you approved) consistent with the science? That is, has the science been used in an arguably appropriate manner?" The SAB is not being asked to agree with -- or to pick -- a particular regulatory level. Rather, they are being asked whether or not the Agency's position is credible, in light of the science.

Note that the review of the Staff Paper is not "peer review" in the classic sense. Rather, it is more of a "lough test" applied to the Agency's use of the science. This statement is not meant to demean the Staff Paper peer review; rather, just as it is an important peer review function to be able to attest to the validity of the science going into a decision, it is equally important for peers to agree that the science was not misused or abused.

Peer Involvement is used to refer to a range of activities that occur early in the development of the Agency's science and the construction of the policy position that is built upon it. Peer involvement can include such things as

- a) The Agency's giving talks about the evolving science positions at professional scientific meetings and engaging in subsequent discussion.

- b) The Agency's conducting a public workshop, soliciting input from the outside scientific community on the technical issues associated with the problem at hand; e.g., the 1993 SRA workshop in San Diego on aspects of the cancer guidelines.
- c) The Agency's commissioning papers on specific aspects an issue; e.g., the writing of chapters for the Dioxin Reassessment.

In going from examples a-c, the involvement from the non-EPA peer becomes more substantial and, hence, that particular peer becomes less appropriate to be a part of the independent peer review that assesses the Agency's final document.

The Range of SAB Activities

The SAB performs both Peer Review and Peer Involvement functions.

a. SAB Peer Review

1. SAB Reviews

The meat-and-potatoes of the SAB's meal is classic peer review of near-final Agency scientific (not policy) documents. There is always a Charge; i.e., a specific set of questions that the Agency wants the SAB to answer during the course of its review. These questions guide, but do not constrain the SAB in its deliberations and in its reports. The SAB deliberates in public and eventually issues its view in a formal written report that goes to the Administrator.

2. SAB Advisories

An SAB Advisory is very similar to an SAB review, but it is applied to an Agency product which that is still evolving within EPA. The subjects of Advisories are usually topics that will be years in the making; e.g., the National Air Toxics Assessment (NATA) program that was the subject of an SAB Advisory last year. Following a two-day public meeting, a written report was prepared and submitted to the Agency. The Agency, in turn, takes the Advisory under -- yes, advisement:) -- and eventually come forward with a final document that the SAB will again review in a similar formal process. In order to insure that that "second-SAB-bite-at-the-apple" is independent and not totally sold out to the suggestions in the Advisory, the SAB endeavors to insure that there is a significant number of participants on the SAB final review panel who are different from those who served on the panel that wrote the Advisory. This process of bringing new faces on board for the final review is a point of some contention with the Agency, since the Agency would naturally prefer not to run the risk of having some "newbees" come in and give them totally different advice. In practice, this fear is rarely manifest.

SAB Peer Involvement

1. SAB Commentaries

An SAB Commentary is a written document that is essentially "unsolicited advice" on a topic that the Board feels should be brought to the Agency's attention. Some people in

the Agency view Commentaries as "the SAB's going off the ranch again"! Others value the fresh perspective on an issue that may have escaped the Agency's attention. A classic example of an SAB Commentary is one written in 1989 about the need for the Agency -- and the other government agencies -- to get its act together in regard to computer models (e.g., fate-and- transport, risk assessment extrapolation, PBPK, etc.) In the Board's mind, there was a proliferation of models with little attention being paid to a wide range of issues including verification, validation, appropriate use of models, choosing among competing models, characterizing uncertainties in the results of models, dealing with proprietary models, articulating limitations in the models to the unwary, etc. When the Agency's efforts to address these problems faltered in the mid-1990s, the SAB issued another Commentary on Models, reiterating and expanding on the concerns. In response, the Agency conducted a productive workshop ("Models 2000") that moved the Agency further in the right direction.

SAB Commentaries are less effective when there is no "customer/champion" for them in the Agency. The Agency already has too many things to do now and cannot follow up on every good idea that some of the best scientific minds in the country can dream up, so the Board needs to be careful to align with its customers -- even if it takes some nudging to get them to see the right line.:)

2. SAB Workshop reports

In recent years, the SAB has begun sponsoring (or co-sponsoring) public workshop designed to spotlight certain issues. For example, the SAB co-sponsored a workshop last year that examined how the community around Tampa Bay made policy decisions that impacted the ecology of the Bay. The goal was to explore different perspectives -- particularly those of the non-economic social sciences; e.g., social anthropology -- on the issue. The result of the public meeting was simply a factual report of events at the workshop, but it did not reach conclusions on the issues nor does it represent a formal SAB position.

3. SAB Consultations

The SAB has been aggressively seeking to become involved in the development of Agency positions very early in the process. The SAB Consultation is a format developed to achieve this end. The Agency approaches the SAB for a Consultation before the Agency's approach to the topic -- let alone a draft position -- has been determined. The Consultation itself is a public meeting in which the Agency describes its problem and the options that it is considering as it moves forward. The SAB panel members, as individuals, then weigh in with their ideas, opinions, perspectives, etc. There is no attempt or intention to reach a consensus of the group. Rather than seeking a common position about what the Board thinks, the Consultation is designed to leaven the Agency's thinking with a range of fresh -- competing or even incompatible -- ideas from smart individuals on the panel. Some of the best Consultations are those in which the members of the panel clearly disagree and forcefully argue their respective positions. The Agency,

listening in the room along with the public, is the beneficiary of the debate. There is no formal report resulting from a Consultation. Hence, the SAB does not "speak", *per se*. The Board simply writes a generic "Notification of an SAB Consultation" letter to the Administrator stating that the Board met with the Agency and shared views on the issue. To the extent that those views become a matter of record, they are captured by Agency personnel and the public in the room, and they are reflected in the minutes of the meeting. Those views, however, are pointedly not recorded in the letter to the Administrator, lest someone interpret a comment in the letter as being an SAB position.

Some confusion arises in the case of Consultations because the same term is used in other contexts with a somewhat different meaning. For example, Congress, in the Safe Drinking Water Act, directs the Agency to "consult" with the SAB at some point during the development of its position. Since the SAB, *per se*, does not speak in an SAB Consultation, the intent of Congress appears to be that the Board conduct a Review or an Advisory in such circumstances.

Conclusion

The SAB, as a group of 100 members and 300+ consultants — none of whom is a Federal employee — plays a vital role in assisting the Agency to develop positions (*e.g.*, regulations, research plans, *etc.*) that are built on a foundation of sound science. To carry out its broad mandate, the SAB has evolved a series of activities that include both peer review and peer involvement. In doing so, the Board has increased the credibility of Agency actions, helped to distinguish risk assessment (science) issues from risk management (policy) issues, and made the decision-making process more open to public scrutiny.